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10/632,158	07/31/2003	Royce S. Fishman	AGALIN 3.0-003 I	2842
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EXAMINER NICHOLSON, KERI JESSICA				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/632,158

**Applicant(s)**

FISHMAN, ROYCE S.

**Examiner**

KERI J. NICHOLSON

**Art Unit**

3772

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59 and 61-167 is/are pending in the application.  
4a) Of the above claim(s) 1-58 and 76-153 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 59, 61-75 and 154-167 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This is the second Office action based on non-provisional application 10/632,158 filed July 31, 2003 for the amendments to the claims filed October 17, 2008 and forwarded to the examiner October 25, 2008 in response to a notice of non-compliance dated October 3, 2008. The amendment to the claims filed September 13, 2007 withdrew claims 1-58, 76-151, cancelled claim 60, and added claims 154-167. The amendments to the claims filed October 17, 2008 withdrew claims 152 and 153. Claims 1-59 and 61-167 are currently pending.

#### ***Abstract***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the use of the implied phrase "are disclosed". Correction is required. See MPEP § 608.01(b).

#### ***Specification***

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Allowable Subject Matter***

4. The indicated allowability of claims 60-75 is withdrawn in view of the new interpretation of Fields et al. (US Patent 2,574,028) as described below.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 63 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

7. Claim 63 recites the limitation "said medical gases" in lines 3-4; however, there is insufficient antecedent basis for this limitation in the claim. For examination purposes, claim 63 has been interpreted to recite "a plurality of medical gases".

8. Claim 66 is dependent from cancelled claim 60 and therefore there is insufficient antecedent basis for "the apparatus". For examination purposes, claim 66 has been interpreted to depend from claim 59.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 59, 66-68, 71, 154-156, and 159 are rejected under 35 U.S.C. 102(b) as being anticipated by Fields et al. (US Patent 2,574,028).

11. Regarding claim 59, Fields discloses an apparatus for the administration of a medical gas to a patient comprising a housing including an upper portion (head, 10) connectable with a lower portion (sleeve, 50) in a configuration in which the housing is closed (Fig. 2), a compressed gas cartridge (container, 60) disposed within the housing and containing a predetermined amount of the medical gas sufficient for normal respiration (column 1, lines 1-6), patient supply means (nozzle, 100) for providing the medical gas to the patient (column 2, lines 34-44), a cassette (housing, 30) (Fig. 1; column 2, lines 17-23), and mounting means including a first acceptance means (rubber washer, 26) compatible with a second acceptance means (flange, 48) on the cassette for mounting the cassette within the housing (column 2, lines 17-21), wherein the compressed gas cartridge is mounted on the cassette (Fig. 2; column 2, lines 24-29), the compressed gas cartridge having a size and configuration whereby the housing may be closed with the compressed gas cartridge disposed within the housing and the compressed gas cartridge can supply the medical gas to the patient from the housing only when the housing is closed (Fig. 2; column 2, lines 17-44).

12. Regarding claim 66, Fields discloses a gas delivery means (needle, 34) in the upper portion of the housing for delivering the medical gas to the patient supply means (column 1, lines 35-42).

13. Regarding claim 67, Fields discloses that the upper portion of the housing further includes a gas control means (spring, 44) for controlling the delivery of the medical gas to the patient supply means (column 2, lines 45-55).

14. Regarding claim 68 and 71, Fields discloses that the gas delivery means includes a blender chamber (chamber, 90) for receiving the medical gas from the compressed gas cartridge at a predetermined pressure and flow rate and gas control means (spring, 44) for

controlling the delivery of the medical gas to the patient supply means (Fig. 2; column 2, lines 37-55).

15. Regarding claim 154, Fields discloses an apparatus for the administration of a medical gas to a patient comprising a housing including an upper portion (head, 10) connectable with a lower portion (sleeve, 50) in a configuration in which the housing is closed (Fig. 2), a compressed gas cartridge (container, 60) disposed within the housing and containing a predetermined amount of the medical gas sufficient for normal respiration (column 1, lines 1-6), patient supply means (nozzle, 100) for providing the medical gas to the patient (column 2, lines 34-44), and gas delivery means (needle, 34) in the upper portion of the housing for delivering the medical gas to the patient supply means (column 1, lines 35-42), wherein the compressed gas cartridge having a size and configuration such that the housing may be closed with the compressed gas cartridge disposed within the housing, the compressed gas cartridge can supply the medical gas to the patient from the housing only when the housing is closed, and the housing can only close if the first acceptance means and the second acceptance means are compatible with each other (Fig. 2; column 2, lines 17-44).

16. Regarding claim 155, Fields discloses that the upper portion of the housing further includes a gas control means (spring, 44) for controlling the delivery of the medical gas to the patient supply means (column 2, lines 45-55).

17. Regarding claim 156 and 159, Fields discloses that the gas delivery means includes a blender chamber (chamber, 90) for receiving the medical gas from the compressed gas cartridge at a predetermined pressure and flow rate and gas control means (spring, 44) for controlling the delivery of the medical gas to the patient supply means (Fig. 2; column 2, lines 37-55).

18. Claim 164 is rejected under 35 U.S.C. 102(b) as being anticipated by Pitesky et al. (US Patent 3,776,227). Pitesky discloses an apparatus for the administration of a medical gas to a patient comprising a housing including an upper portion (head, C) connectable with a lower portion (housing, D) in a configuration in which the housing is completely closed (Fig. 2), a compressed gas cartridge (E) disposed within the housing and containing a predetermined amount of the medical gas sufficient for normal respiration (column 1, lines 58-60), and patient supply means (mouthpiece, B) for providing the medical gas to the patient (Fig. 1; column 2, lines 12-15), wherein the compressed gas cartridge is fully enclosed within the housing whereby access to the compressed gas cartridge is prevented (Fig. 2; column 3, lines 38-40).

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fields as applied to claim 59 above in view of Ritson et al. (US Patent 5,520,166). Fields discloses the invention substantially as claimed, as described above, but fails to teach that the first acceptance means and the second acceptance means comprise a plurality of corresponding key means consisting of male members and female members.

Ritson discloses a medication delivery system comprising a housing (body, 2), a cassette (housing, 40) disposed within the housing, a compressed gas cartridge (canister, 30) mounted on the cassette, patient supply means (mouthpiece, 20), and mounting means including a plurality of first acceptance means (keyplate, 440) compatible with a plurality of

second acceptance means (protrusions, 48) on the cassette in the form of male and female members for mounting the cassette within the housing (Figs. 3-9; column 11, lines 52-63). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the first and second acceptance means of the apparatus taught by Fields to include a plurality of key means consisting of corresponding male and female members as taught by Ritson for the purpose of preventing the insertion of the wrong or an unauthorized medication into the housing.

21. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fields as applied to claim 59 above in view of Zihnerl et al. (US Patent 2,944,547). Fields discloses the invention substantially as claimed, as described above, but fails to teach a plurality of compressed gas cartridges containing a plurality of medical gases.

Zihnerl discloses a portable inhalator comprising a housing (A) and a plurality of compressed gas cartridges (46, 49) disposed within the housing and containing a plurality of medical gases (Figs. 1 & 4; column 2, lines 47-49; column 3, lines 12-13, 38-39, 42-44, & 50-52; column 6, lines 52-72). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by Fields to further comprise a plurality of compressed gas cartridges as taught by Zihnerl for the purpose of providing a mixture of medical gases to the patient simultaneously.

22. Claims 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fields as applied to claim 59 above, in view of Zihnerl as applied to claim 63 above, and in further view of Ritson et al. (US Patent 5,520,166). The combination of Fields and Zihnerl discloses the invention substantially as claimed, as described above, but fails to teach that the first



acceptance means and the second acceptance means comprise a plurality of corresponding key means consisting of male members and female members.

Ritson discloses a medication delivery system comprising a housing (body, 2), a cassette (housing, 40) disposed within the housing, a compressed gas cartridge (canister, 30) mounted on the cassette, patient supply means (mouthpiece, 20), and mounting means including a plurality of first acceptance means (keyplate, 440) compatible with a plurality of second acceptance means (protrusions, 48) on the cassette in the form of male and female members for mounting the cassette within the housing (Figs. 3-9; column 11, lines 52-63). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the first and second acceptance means of the apparatus taught by Fields to include a plurality of key means consisting of corresponding male and female members as taught by Ritson for the purpose of preventing the insertion of the wrong or an unauthorized medication into the housing.

23. Claims 69, 72, 74, 157, 160, and 162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fields as applied to claims 59, 66-68, 71, 154-156, and 159 above in view of Psaros (US Patent 6,286,505).

24. Regarding claims 69, 72, 157, and 160, Fields discloses the invention substantially as claimed, as described above, but fails to teach that the gas control means comprises a gas control sensor for sensing the content and pressure of the medical gas, and valve means for terminating the supply of the medical gas based on the sensed content and pressure of the medical gas.

Psaros discloses a portable anaesthetic machine (38) comprising a compressed gas cartridge (gas cylinder, 18) containing a medical gas, a gas control sensor (gas analyzer, 22) for

measuring the gas concentrations of the medical gas, a control unit (38) for controlling a valve (40) and the dispensing of the medical gas to the user based on measurements of the gas control sensor, and pressure gauges (42, 44) for supplying the control unit with pressure information (column 3, lines 9-20 & 36-54). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by Fields to further comprise a gas control sensor and pressure gauges as taught by Psaros to ensure that the correct gas dosages are being delivered to the patient at the correct pressure. Since the parameters for the control unit are set by the user, it would have been obvious that the user could also set the control unit to terminate the supply of the medical gas based on the sensed content and pressure of the medical gas for preventing an incorrect dosage from being delivered to the patient.

25. Regarding claims 74 and 162, the combination of Fields and Psaros discloses the invention substantially as claimed, as described above, but fails to teach a second gas control means for sensing the pressure leaving the blender chamber. At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of Fields and Psaros to have a second gas control means such as a pressure gauge as taught by Psaros for sensing the pressure leaving the blender chamber for the purpose of ensuring that the medical gas is being delivered to the patient at the correct pressure. Further, it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

26. Claims 70, 73, 75, 158, 161, and 163 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fields as applied to claims 59, 66-68, 71, 154-156, and 159 above, in view of

Psaros as applied to claims 69, 72, 74, 157, 160, and 162 above, and in further view of Landis et al. (US Patent 4,648,393).

27. Regarding claims 70, 73, 158, and 161, the combination of Fields and Psaros discloses the invention substantially as claimed, as described above, but fails to teach room air breathing means, whereby upon terminating of the supply of the medical gas, the room air breathing means supplies room air for breathing by the patient.

Landis discloses an inhalation device comprising a housing (case, 10), a compressed air cartridge (canister, 94) disposed within the housing, patient supplies means (mouthpiece, 16), and room air breathing means (intake opening, 70) for supplying room air for breathing by the patient (Figs. 1-4; column 4, lines 4-6). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of Fields and Psaros to further comprise room air breathing means as taught by Landis such that the patient may be able to breath in ambient air when the control unit terminates the supply of medical gas to the patient for the purpose of maintaining sufficient oxygen levels to the patient even when the flow of the medical gas is restricted.

28. Regarding claims 75 and 163, the combination of Fields and Psaros discloses the invention substantially as claimed, as described above, but fails to teach that the gas control means comprises an air inlet port for permitting air to enter the housing for delivery to the patient supply means and an air intake valve for controlling the entry of the air when the valve means terminates the supply of the medical gas.

Landis discloses an inhalation device comprising a housing (case, 10), a compressed air cartridge (canister, 94) disposed within the housing, patient supplies means (mouthpiece, 16), and an air inlet port (intake opening, 70) for permitting air to enter the housing for delivery to the patient supply means (Figs. 1-4; column 4, lines 4-6). At the time the invention was made, it

would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of Fields and Psaros to further comprise an air inlet port as taught by Landis such that the patient may be able to breath in ambient air when the control unit terminates the supply of medical gas to the patient for the purpose of maintaining sufficient oxygen levels to the patient even when the flow of the medical gas is restricted. However, the combination of Fields / Psaros / Landis fails to expressly teach an air intake valve for controlling the entry of the air.

Psaros teaches the use of an expiratory valve (26) to control flow through the expiratory line (8). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by the combination of Fields / Psaros / Landis to further comprise an air intake valve for controlling the entry of the air since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

29. Claims 165-167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pitesky as applied to claims 164 above in view of Ritson et al. (US Patent 5,520,166). Pitesky discloses the invention substantially as claimed, as described above, but fails to teach a cassette on which the gas cartridge is mounted and mounting means for mounting the cassette within the housing.

Ritson discloses a medication delivery system comprising a housing (body, 2), a cassette (housing, 40) disposed within the housing, a compressed gas cartridge (canister, 30) mounted on the cassette, patient supply means (mouthpiece, 20), and mounting means including a plurality of first acceptance means (keyplate, 440) compatible with a plurality of second acceptance means (protrusions, 48) on the cassette in the form of male and female members for mounting the cassette within the housing (Figs. 3-9; column 10, lines 19-26;

column 11, lines 52-63). At the time the invention was made, it would have been obvious to one having ordinary skill in the art to modify the apparatus taught by Pitesky to include a cassette on which the compressed gas cartridge is mounted with a plurality of acceptance means that are compatible with a plurality of acceptance means on the housing for placement of the cassette in the housing as taught by Ritson for the purpose of providing for identification of medication and preventing the insertion of the wrong or an unauthorized medication into the housing.

### ***Double Patenting***

30. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

31. Claims 1-26 of this application conflict with claims 1-26 of Application No. 11/599,582. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

### ***Response to Arguments***

32. Applicant's arguments filed September 13, 2008 have been fully considered but they are not persuasive.

33. Regarding Applicant's argument that Fields does not teach that the container (60) is contained within a closed housing, the examiner agrees. However, this limitation is not required by claims 59, 61-75, and 154-163. Further, newly added independent claim 164 is rejected over Pitesky as described above.

34. Regarding Applicant's argument that Fields does not teach gas delivery means in the upper portion of the housing for delivering the medial gas to the patient supply means, the examiner disagrees. Fields teaches a needle (34) in the upper portion of the housing which delivers the medical gas to the nozzle (100), wherein the release of the gas is controlled by the user compressing a spring (44) via arms (45) (column 1, lines 35-42).

35. In response to Applicant's argument that Fields does not teach an apparatus that is capable of the most preferred used of the Applicant's present invention, it is noted that the features upon which Applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI J. NICHOLSON whose telephone number is 571-270-3821. The examiner can normally be reached on Monday - Thursday, 8am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached at 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJN

/Keri J. Nicholson/

Examiner, Art Unit 3772

1/6/2009

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772